

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

SANOFI-AVENTIS §
DEUTSCHLAND GMBH, §
§
Plaintiff, §
§
vs. § Case No. _____
§
NOVO NORDISK INC. §
§
Defendant. § § **TRIAL BY JURY DEMANDED**
§

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Sanofi-Aventis Deutschland GmbH ("SANOFI-AVENTIS") hereby complains of Defendant, Novo Nordisk Inc. ("NOVO"), as follows:

PARTIES

1. SANOFI-AVENTIS is a corporation organized and existing under the laws of Germany, with offices located at Brüningstrasse 50, D-65929 Frankfurt am Main, Germany.
2. On information and belief, Novo Nordisk Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal office located at 100 College Road, Princeton, New Jersey.

JURISDICTION AND VENUE

3. The present action alleges infringement of a United States Patent under 35 U.S.C. § 271, including at least § 271(a), § 271(b) and § 271(c).

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

5. The Court has personal jurisdiction over NOVO. NOVO has purposefully and voluntarily placed its infringing products into the stream of commerce with the expectation that these products will be purchased by consumers in this judicial district. NOVO has done so as part of its continuous and systematic general business contacts with this judicial district. These products have been and continue to be purchased by consumers in this judicial district.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400.

FACTS

7. SANOFI-AVENTIS is a leading international pharmaceutical company that strives to meet a wide array of healthcare needs through innovative products, such as insulin and insulin delivery devices for the treatment of diabetes.

8. Haselmeier GmbH ("Haselmeier") of Stuttgart, Germany is a research and development company. One of Haselmeier's principals, Mr. Jochen Gabriel, along with another Haselmeier employee, Mr. Ulf Polzin, invented an improved safety needle that reduced patient injection anxiety and eliminated post injection accidental needle sticks. Haselmeier, through its BD Medico subsidiary, filed and obtained patent rights for its improved safety needle, including U.S. Patent No. 6,203,529 ("the '529 Patent"), which issued on March 20, 2001. The '529 Patent pertains, among other things, to the design of a needle assembly for injection devices that eliminates anxiety in patients and prevents accidental needle sticks after use. A true and correct copy of the '529 Patent is attached hereto as Exhibit 1.

9. On or about March 25, 1999 the name BD Medico was changed to Haselmeier S.à.r.l. On or about March 20, 2008, Haselmeier S.à.r.l changed its name to Haselmeier GmbH. On April 1, 2008, Haselmeier GmbH assigned all rights in the '529 Patent to Sanofi-Aventis Deutschland GmbH such that SANOFI-AVENTIS is the owner of all right, title and interest in and to the '529 Patent with the right to recover damages for all past infringement of the '529 patent.

10. On information and belief, NOVO purports to be an international healthcare company that focuses on diabetes care. In the United States, Novo markets both disposable and reusable insulin delivery devices and sells a variety of needle products. One such needle product is the NovoFine® Autocover® safety needle.

11. On information and belief, NOVO has imported the NovoFine® Autocover® safety needle into the United States and has offered for sale and sold the NovoFine® Autocover® safety needle throughout the United States, including in this judicial district, since at least 2007.

PATENT INFRINGEMENT—'529 PATENT

12. SANOFI-AVENTIS incorporates herein by reference the allegations of paragraphs 1 through 11.

13. The NovoFine® Autocover® safety needle infringes claims of the '529 Patent in violation of 35 U.S.C. § 271.

14. The NovoFine® Autocover® safety needle literally infringes at least claim 1 of '529 Patent because each of the claimed elements is found in the NovoFine® Autocover® needle product.

15. NOVO's NovoFine® Autocover® safety needle also infringes at least claim 1 under the doctrine of equivalents because parts and materials of construction of the NovoFine® Autocover® needle product perform substantially the same function, in substantially the same way, to obtain substantially the same result as the materials and parts claimed in the '529 patent.

16. Upon information and belief, NOVO was aware of the '529 Patent prior to the commission of some or all of the infringing acts alleged herein, and its infringement has been and continues to be reckless, egregious and willful.

17. As a result of the infringement by NOVO, SANOFI-AVENTIS has been, is being and will continue to be irreparably harmed.

18. NOVO's reckless, egregious and willful infringement of the '529 Patent makes this an exceptional case under 35 U.S.C. § 285.

WHEREFORE, SANOFI-AVENTIS prays for judgment that:

- A. NOVO has infringed claims of United States Patent No. 6,203,529;
- B. NOVO, its officers, agents, servants and employees, and those persons in active concert and participation with any of them, be preliminarily and permanently enjoined from further infringement of United States Patent No. 6,203,529;
- C. SANOFI-AVENTIS be awarded damages sufficient to compensate it for the infringement, but in no event less than a reasonable royalty for such infringement, and that such damages be increased to three times the amount found or assessed pursuant to 35 U.S.C. § 284, together with prejudgment interest;
- D. This case be declared exceptional pursuant to 35 U.S.C. § 285 and that SANOFI-AVENTIS be awarded its attorneys' fees, costs and expenses in this action; and

E. SANOFI-AVENTIS be awarded such other and further relief as the Court may deem just.

DEMAND FOR JURY TRIAL

SANOFI-AVENTIS hereby demands a jury trial on all issues.

Respectfully submitted,

Date: 9 January, 2009



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EXHIBIT 1

U.S. Patent

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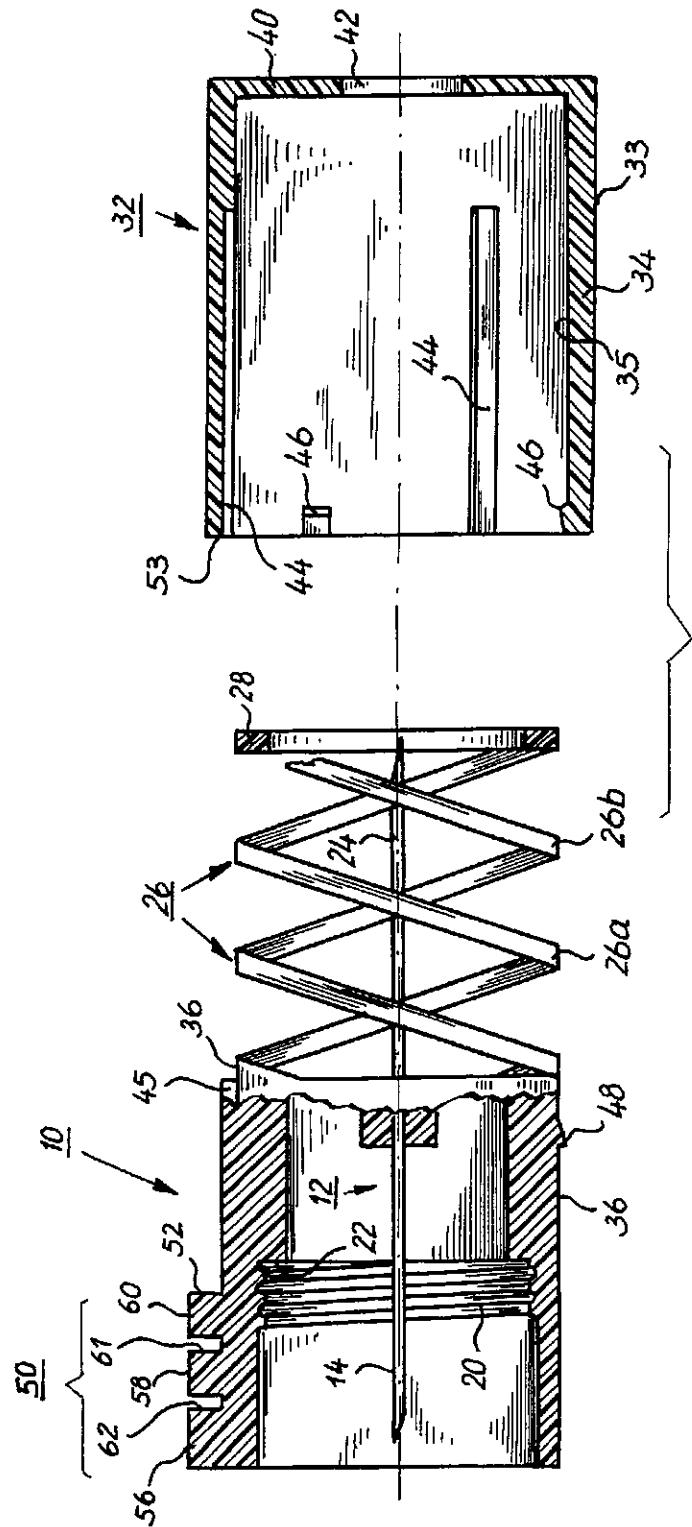


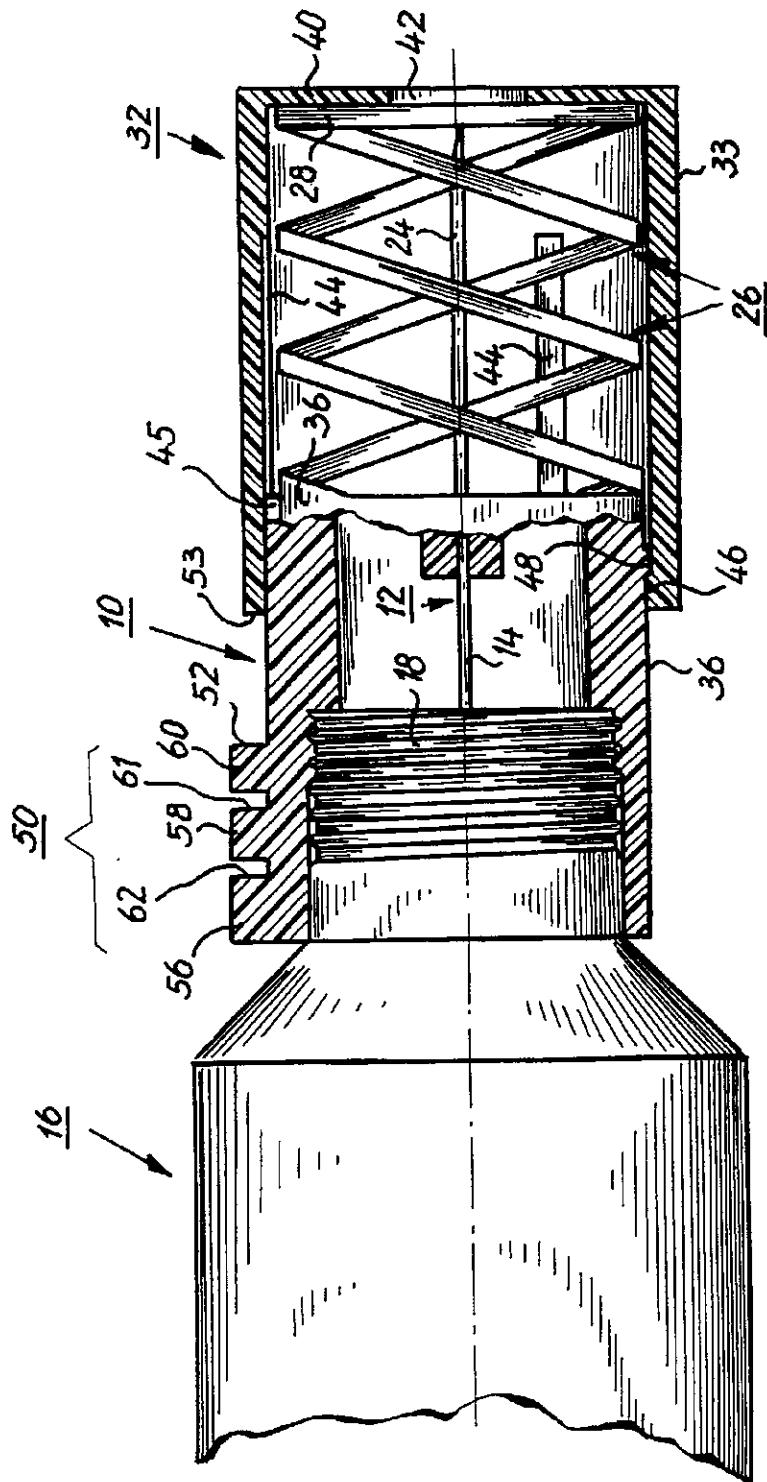
Fig. 1

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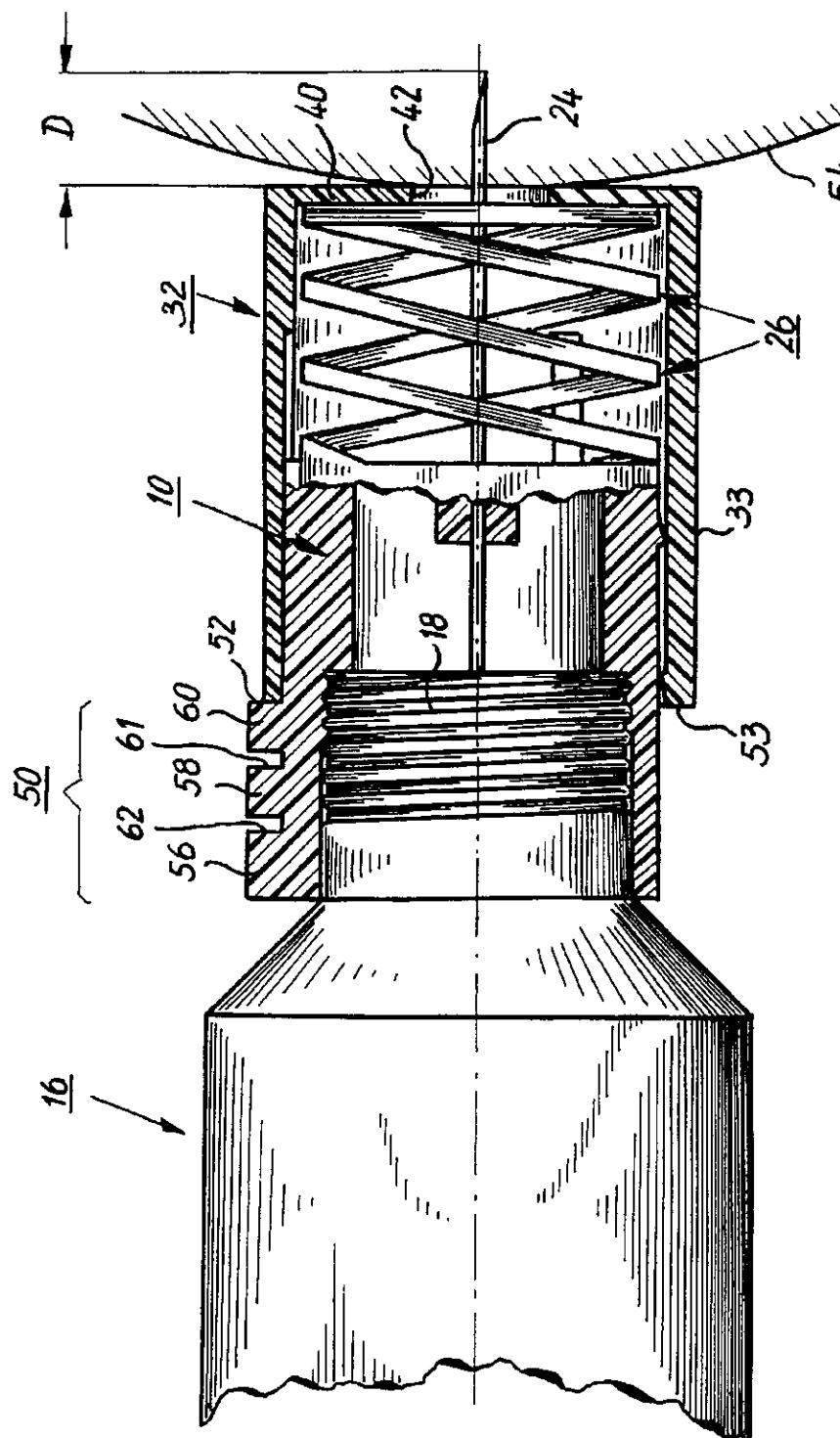


Fig. 3

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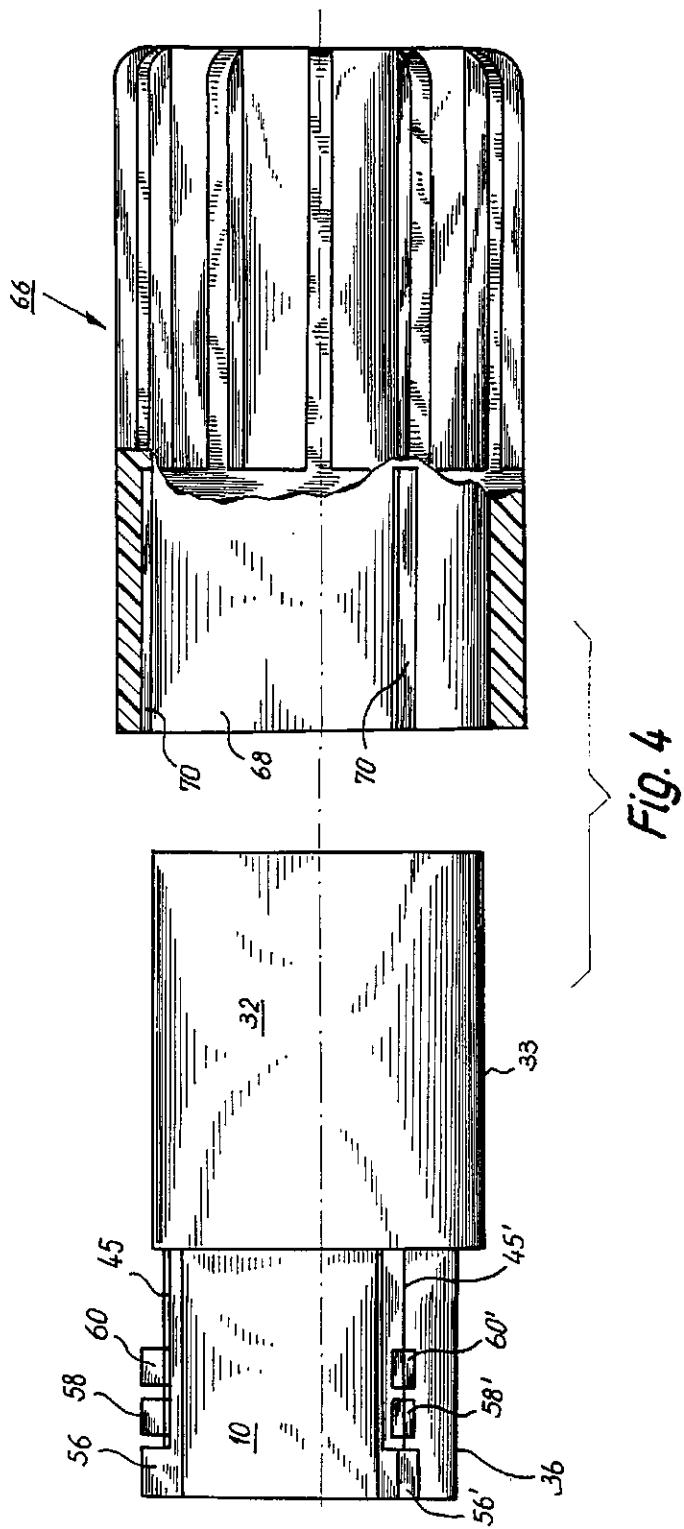


Fig. 4

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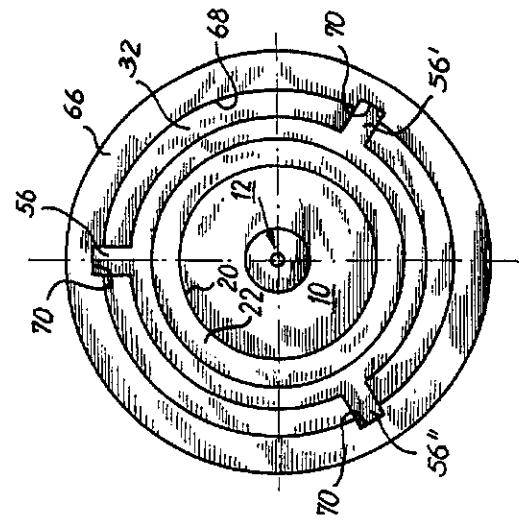


Fig. 6

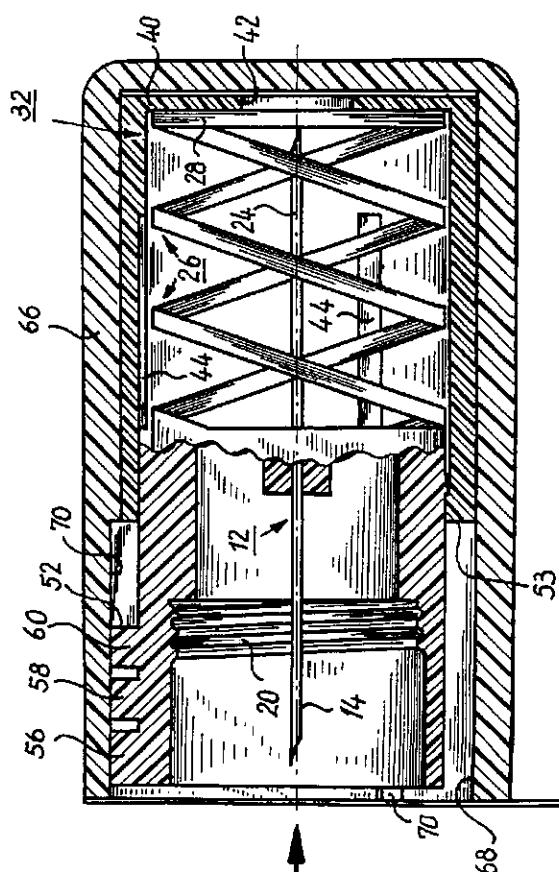


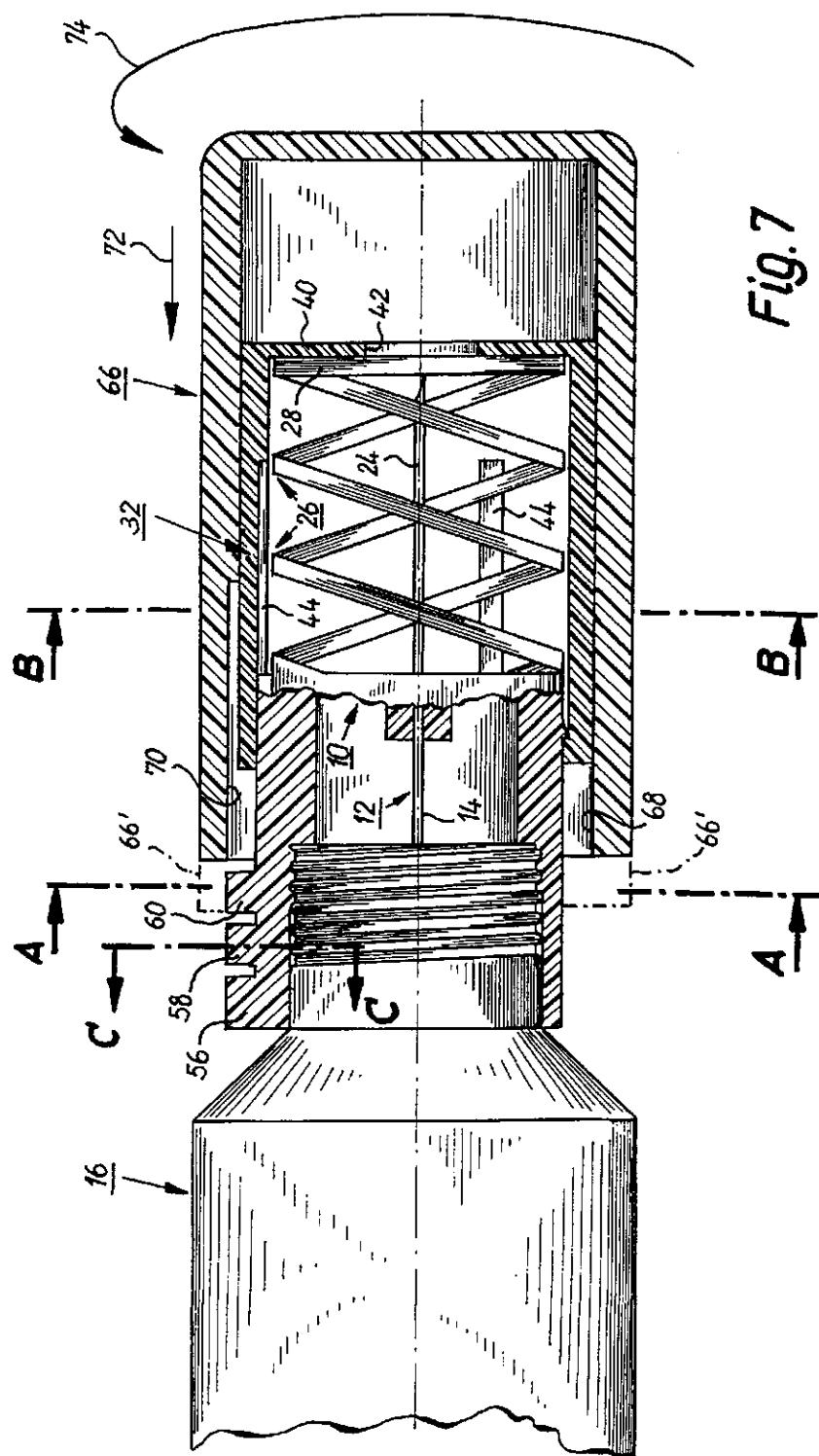
Fig. 5

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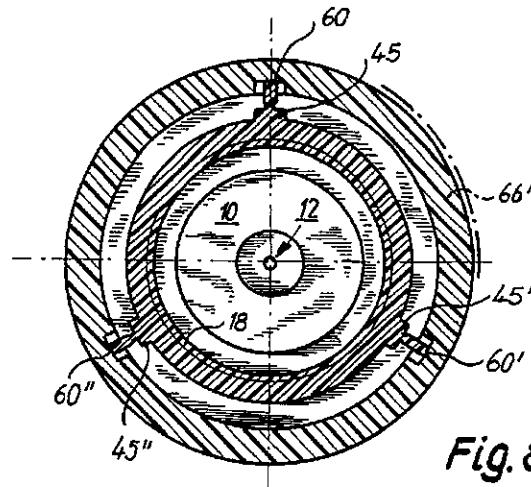


Fig. 8

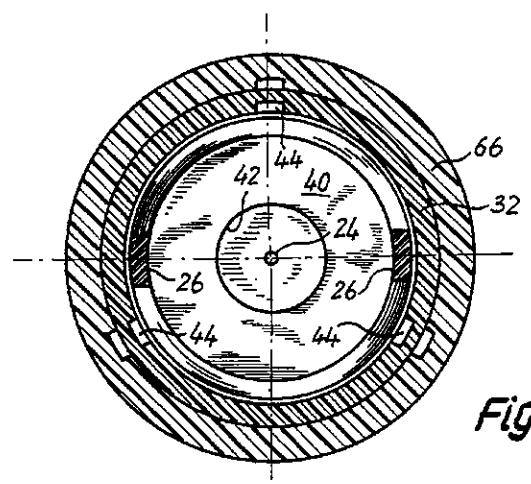


Fig. 9

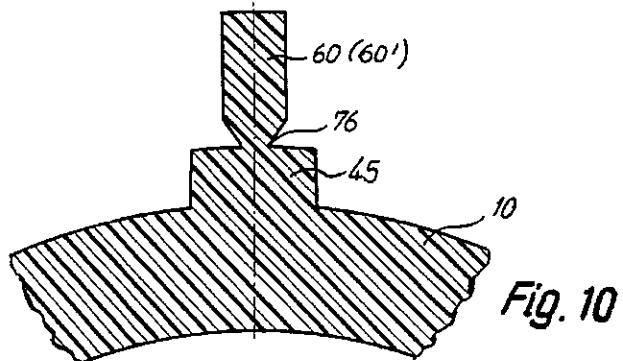


Fig. 10

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NEEDLE ARRANGEMENT

FIELD OF THE INVENTION

The invention relates to a needle arrangement for an injection device.

BACKGROUND

A needle arrangement of this kind is known from EP 0 749 758 A1, HJERTMAN et al. In it, a hollow needle that is mounted on a hollow needle holder is used. The latter is screwed onto an external thread at the proximal end of the injection device. A special apparatus which makes the hollow needle invisible to the user, so as to eliminate his or her anxiety regarding injections, is then slid over this hollow needle.

SUMMARY OF THE INVENTION

It is the object of the invention to make available a new needle arrangement for an injection device.

According to the invention, this object is achieved by providing a compressible spring surrounding the needle, and a generally cylindrical open-ended first cap which fits over the spring.

A needle arrangement of this kind is very easy to utilize, since in practice it uses nothing more than a replaceable hollow needle. Easy adjustment of the penetration depth is also achieved, since the necessary penetration depth may be different depending on the patient's constitution. In this instance, it can be adjusted easily and obviously.

Another manner of achieving the stated object is to make the spring of plastic material, and form it integrally with a hollow needle carrier.

An arrangement of this kind has only a few parts and thus can be produced very economically. It can be used by the patient in a simple, easily understandable fashion.

A further manner of achieving the stated object is to provide a second covering cap which surrounds the first cap, the needle, and the needle carrier, and is sealed closed by a peelable foil, thereby keeping the surrounded elements sterile until the user peels off the foil.

A needle arrangement of this kind can very easily be kept sterile until used. The covering cap is usable as an assembly aid, additionally facilitating use by the patient.

Each time the patient thrusts the hollow needle in prior to an injection, the displaceable cap is displaced in the distal direction against the force of the spring, and when the hollow needle is pulled out it moves back into its proximal end position under the action of the spring, so that the patient does not see the hollow needle during the entire injection procedure. Because of the detachable mounting on the injection device, a needle arrangement of this kind can very easily be replaced, after an injection, with a new, sterile needle arrangement.

BRIEF FIGURE DESCRIPTION

Further details and advantageous developments of the invention are evident from the exemplary embodiment, which is described below and depicted in the drawings and is in no way to be understood as a limitation of the invention, and from the dependent claims. In the drawings:

FIG. 1 is a longitudinal section through a preferred embodiment of a needle arrangement according to the present invention, in an exploded and greatly magnified depiction;

FIG. 2 shows a view similar to that of FIG. 1 but in the assembled state, the hollow needle being concealed by the arrangement;

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FIG. 3 shows a view similar to that of FIG. 2 but with the needle thrust in, the penetration depth being labeled D;

FIG. 4 shows a view similar to that of FIG. 2, additionally depicting an outer covering cap 66 which serves to encase the needle arrangement in sterile fashion;

FIG. 5 shows a view of a complete, packaged needle arrangement according to a preferred embodiment of the invention;

FIG. 6 is a plan view looking in the direction of arrow VI of FIG. 5;

FIG. 7 is a view showing the adjustment of the penetration depth by way of the external covering cap 66;

FIG. 8 is a sectional view along line A—A of FIG. 7;

FIG. 9 is a sectional view along line B—B of FIG. 7; and

FIG. 10 is a sectional view through a defined breakpoint for a stop element, viewed along line C—C of FIG. 7.

DETAILED DESCRIPTION

In the description that follows, the terms "proximal" and "distal" will be used in the manner usual in medicine, to wit:

"Proximal"=facing toward the patient (the end of the injection device having the needle);

"distal"=facing away from the patient.

FIG. 1 shows, on the left, a hollow needle carrier 10 made of a suitable plastic, e.g. polyethylene. Secured in this is a hollow needle (injection needle) 12 whose distal end 14 serves to pierce through the rubber membrane (not depicted) on the reservoir of an injection device 16 that is indicated only schematically in FIGS. 2 and 3.

An inner thread 20 of hollow needle 10, which is delimited in the proximal direction by a shoulder 22 serving as a stop, provides detachable mounting on an external thread 18 at the proximal end of injection device 16.

The proximal segment of hollow needle 12 is labeled 24. Extending concentrically around it, in the arrangement as shown in FIG. 1, is a plastic spring 26 that can be configured integrally with hollow needle carrier 10 and that here comprises two helical springs or spirals 26a, 26b, offset 180°, which each transition at their proximal end into a ring 28 with which they can also be integrally configured. Alternatively a separate spring, for example made of metal, could also be used here.

A first sleeve or cap 32 has a substantially cylindrical segment 34 whose cylindrical outer side is labeled 33 and whose cylindrical inner side 35 is configured for sliding displacement on the (also cylindrical) circumference 36 of hollow needle carrier 10. First cap 32 furthermore has at proximal end a base 40 in whose center is located a recess 42 through which proximal end 24 of hollow needle 12 can pass during an injection, as shown in FIG. 3.

First cap 32 has on its inner side 35 a total of three longitudinal grooves 44, only two of which are visible in FIG. 1, uniformly distributed on the circumference and providing axial guidance, i.e. rotation prevention. They coact with three projections 45, complementary thereto, on the cylindrical outer circumference 36 of hollow needle carrier 10, as clearly shown by FIGS. 2 and 3.

First cap 32 furthermore has three barbs 46 on its inner circumference 35. These barbs are also uniformly distributed on the circumference, and coact with three corresponding complementary barbs 48 on outer circumference 36 of hollow needle 10, only one of which is visible in FIG. 1.

During assembly, barbs 46 slide over barbs 48 so that parts 10 and 32 are joined to one another nondetachably but axially displaceably; barbs 46, 48 form a stop in the prox-

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mal direction, as depicted in FIG. 2, and grooves 44 coact with the complementary projections 45 to provide rotation prevention for first cap 32, so that the latter cannot rotate relative to hollow needle carrier 10.

As clearly shown in FIGS. 1 through 3, there is located on outer circumference 36 of hollow needle carrier 10 a stop arrangement 50 against whose proximal shoulder 52 (as shown in FIG. 3) first cap 32 comes to rest with its distal end 53 when hollow needle 12 is thrust with its proximal end 24 into a body part 54 (indicated only schematically).

Stop arrangement 50 has here a distal stop element 56, a central stop element 58, and a proximal stop element 60. At least proximal stop element 60 and central stop element 58 are each joined integrally to hollow needle carrier 10 by way of a defined break point 76 (FIG. 10), and consequently can be broken off from hollow needle carrier 10 by the user. This increases insertion depth D (FIG. 3) of the proximal hollow needle portion 24. Thus either it is possible to break off only stop element 60, so that first cap 32 then comes to rest against a shoulder 61 when hollow needle 12 is thrust in; or both stop elements 58 and 60 can be broken off, in which case first cap 32 then comes to rest against a shoulder 62 when hollow needle 12 is thrust in. In the latter case, the maximum penetration depth is attained.

FIG. 4 shows, at left, hollow needle carrier 10 on whose circumference stop elements 56, 58, 60 and 56, 58', 60, 56", etc. are arranged at uniform spacings of 120°. FIG. 6 shows the three stop elements 56, 56', and 56" in a plan view according to arrow VI of FIG. 5.

FIG. 4 shows that an outer covering cap 66, which provides sterile covering of the needle arrangement, is also provided. Outer covering cap 66 is depicted in FIG. 4 partially in longitudinal section, and it is evident that its cylindrical inner recess 68, which in the case of the complete needle arrangement shown in FIGS. 5 and 6 is slid over the cylindrical outer side 33 of first cap 32, has three longitudinal grooves 70 which are distributed uniformly on the circumference of inner recess 68 and are dimensioned such that they can be slid over stop elements 56, 58, 60, 56', 58", 60', 56" etc., as is particularly clearly evident from FIG. 6.

FIG. 5 also shows a protective film 71 with which, in the complete needle arrangement, the opening (FIG. 5, left) of outer covering cap 66 can be sealed in sterile fashion. This film is welded on or adhesively bonded on, and is torn off before use. Film 71 is not depicted in FIG. 6.

FIG. 7 shows how outer covering cap 66 can be slid axially onto first cap 32 in the direction of arrow 72, arriving at a position 66' which is indicated in FIG. 7 with dot-dash lines and is depicted in section in FIG. 8, and in which its longitudinal grooves 70 are in engagement with stop elements 60, 60', 60". If outer covering cap 66 is then rotated in the direction of rotation arrow 74 depicted in FIG. 7, stop elements 60, 60', 60" are broken off along their defined break points 76 (cf. FIG. 10), i.e. penetration depth D (FIG. 3) is correspondingly increased in the manner already described above. In the same manner, it is also possible to break off both stop elements 58, 60 (correspondingly 58', 60', etc.), and thereby to increase penetration depth D even further.

What is described is thus a needle arrangement for an injection device 16. It has a hollow needle carrier 10 on which a hollow needle 12 is mounted and which is configured for detachable mounting on injection device 16. The arrangement has a cap 32 that is arranged on hollow needle carrier 10 displaceably approximately parallel to the longitudinal extension of hollow needle 12, is equipped at its proximal end segment with a passthrough opening 42 for hollow needle 12, and in its proximal end position substan-

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tially conceals hollow needle 12. A compression spring 26 is arranged between hollow needle carrier 10 and cap 32 in order to displace cap 32 into its proximal end position. Also provided is a covering cap 66 which surrounds the displaceable cap 32, hollow needle 12, and hollow needle carrier 10, and on its open side is sealed in sterile fashion by a tear-off sealing member 71. A needle arrangement of this kind can easily be replaced after an injection. It improves compliance because the patient does not at any time see hollow needle 12. The compression spring can be configured as plastic spring 26. It is preferably integral with hollow needle carrier 10, which simplifies manufacture.

Many other variants and modifications are, of course, also possible within the scope of the present invention.

What is claimed is:

1. A needle arrangement for an injection device (16), having a hollow needle carrier (10) on which a hollow needle (12) is mounted and which is configured for mounting on an injection device (16); having a first cap (32) which is arranged on the hollow needle carrier (10) and is displaceable approximately parallel to the longitudinal extension of the hollow needle (12) between a distal and a proximal end position, is formed at its proximal end segment with a passthrough opening (42) for the hollow needle (12), and in its proximal end position substantially conceals the hollow needle (12); having a compression spring (26), arranged between the hollow needle carrier (10) and the first cap (32), for displacing the first cap (32) into its proximal end position; having a second cap (66) adapted to surround said displaceable first cap (32), said hollow needle (12) and said hollow needle carrier (18), and having a user-removable protective barrier (71) closing off an open side of said second cap, whereby said second cap (66) and said protective barrier together form a sterile enclosure around said first cap (32), said hollow needle (12) and said needle carrier (10).
2. The needle arrangement as defined in claim 1, wherein said hollow needle carrier (10) is formed with an internal thread (20) for engagement with an external thread (18) formed on a surface of an associated injection device (16).
3. The needle arrangement as defined in claim 1, wherein said cover cap (66) has a form adapted for transfer of torque to said hollow needle carrier (10).
4. The needle arrangement as defined in claim 3, wherein said cover cap (66) is shaped for form-locking engagement with said hollow needle carrier (10).
5. The needle arrangement according to claim 1, wherein said user-removable protective barrier (71) is a peelable foil bonded across said open side of said second cap (66).
6. The needle arrangement according to claim 1, wherein an outer surface (36) of said hollow needle carrier (10) is formed with at least two stop elements (58, 60, 58', 60') serving to limit axial displacement of said first cap (32), said stop elements being frangible from said needle carrier at respective breakpoints (76) formed therein.
7. The needle arrangement according to claim 6, wherein the cover cap (66) has a form adapted to influence at least one stop member (58, 60, 58', 60') formed on an outer surface of said hollow needle carrier (10) in order to set a penetration depth (D) of said needle.
8. The needle arrangement as defined in claim 7, wherein the at least one stop member (58, 60) is mounted on the hollow needle carrier (10) via a defined breakpoint (76) at which said stop member can be broken off by a rotational

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motion (74) of the covering cap (66, 66') brought into engagement with said stop member.

9. The needle arrangement as defined in claim 6, wherein said breakpoint serves as a axial guide for displacement of said first cap (32) relative to said hollow needle carrier (10).

10. The needle arrangement according to claim 1, wherein the first cap (32) is arranged displaceably on a substantially cylindrical circumferential surface (36) of the hollow needle carrier (10), and a rotation preventer (44, 45) is provided between the hollow needle carrier (10) and the first cap (32).

11. The needle arrangement according to claim 10, wherein said rotation preventer includes a longitudinal groove (44), formed on one of said first cap (32) and said needle carrier (10), and a complementary projection (45), adapted to engage in said groove (44), formed on the other of said first cap (32) and said needle carrier (10).

12. The needle arrangement according to claim 1, wherein said compression spring (26) is formed of plastic material.

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13. The needle arrangement as defined in claim 12, wherein said plastic spring is formed integrally with said needle carrier (10).

14. The needle arrangement according to claim 12, wherein said plastic spring (26) has a proximal end formed as a ring (32), said ring engaging against said first cap (32) and urging said cap in a proximal direction.

15. The needle arrangement as defined in claim 14, wherein the ring (28) is formed integrally with said plastic spring (26).

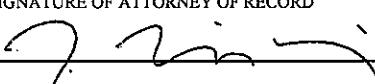
16. The needle arrangement as defined in claim 12, wherein the plastic spring (26) includes a pair of helical spring elements (26a, 26b), each formed integrally with said hollow needle carrier (10).

* * * * *

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS SANOFI-AVENTIS DEUTSCHLAND GMBH		DEFENDANTS NOVO NORDISK INC.	
(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)		County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)	
(c) Attorney's (Firm Name, Address, and Telephone Number) Germér Gertz LLP 550 Fannin, Suite 400 Beaumont, Texas 77701		Attorneys (If Known)	
II. BASIS OF JURISDICTION (Place an "X" in One Box Only)		III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant) (For Diversity Cases Only)	
<input type="checkbox"/> 1 U.S. Government Plaintiff	<input checked="" type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)	Citizen of This State <input type="checkbox"/> PTF <input type="checkbox"/> DEF	Incorporated or Principal Place of Business In This State <input type="checkbox"/> PTF <input type="checkbox"/> DEF
<input type="checkbox"/> 2 U.S. Government Defendant	<input type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	Citizen of Another State <input type="checkbox"/> 2 <input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State <input type="checkbox"/> 5 <input type="checkbox"/> 5
		Citizen or Subject of a Foreign Country <input type="checkbox"/> 3 <input type="checkbox"/> 3	Foreign Nation <input type="checkbox"/> 6 <input type="checkbox"/> 6
IV. NATURE OF SUIT (Place an "X" in One Box Only)			
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REAL PROPERTY		CIVIL RIGHTS	
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		PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	
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OTHER STATUTES <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/ Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes			
V. ORIGIN (Place an "X" in One Box Only)		Appeal to District Judge from Magistrate Judgment	
<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened <input type="checkbox"/> 5 Transferred from another district (specify) <input type="checkbox"/> 6 Multidistrict Litigation <input type="checkbox"/> 7
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 35 U.S.C. 271			
Brief description of cause: Patent Infringement			
VI. CAUSE OF ACTION		DEMANDS	
VII. REQUESTED IN COMPLAINT:		<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23	CHECK YES only if demanded in complaint: JURY DEMAND: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
VIII. RELATED CASE(S) IF ANY		(See instructions): JUDGE DOCKET NUMBER	
DATE	SIGNATURE OF ATTORNEY OF RECORD		
01/09/2009			
FOR OFFICE USE ONLY			
RECEIPT #	AMOUNT	APPLYING IFP	JUDGE
			MAG. JUDGE